

Applicants: Beth Borowsky, et al  
U.S. Serial No.: 09/899,732  
Filed: July 5, 2001  
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REMARKS

**Restriction Requirement**

On page 2 of the September 30, 2002 Office Action, the Examiner requested restriction to one of the following alleged inventions under 35 U.S.C. §121:

- I. Claims 198-207 and 214, drawn to a method of treating depression in a subject comprising administering a MCH1 antagonist, classified in class 514, subclass 2; and
  
- II. Claims 208-213, drawn to a method of treating anxiety in a subject comprising administering a MCH1 antagonist, classified in class 514, subclass 2.

The Examiner alleged that inventions I and II are related in that they are both methods of treatment comprising administration of an antagonist to MCH1, however, depression and anxiety are two separate and distinct diseases that are diagnostically classified as separate and distinct diseases by the DSM (Diagnostic and Statistical Manual of Mental Disorders), and therefore methods of treatment are patently distinct. The Examiner further alleged that since these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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In response to this restriction requirement, applicants hereby elect, with traverse, to prosecute the invention of Group I, claims 198-207 and 214. Applicants note that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicants respectively directs the Examiner to page 680 of the DSM-IV-TR (Diagnostic and Statistical Manual of Mental Disorders. Section 309.28 on page 680 describes an adjustment disorder as comprising of both anxiety and depressed mood. A copy of page 680 is attached hereto as **Exhibit A**. The DSM describes this disorder as "when the predominant manifestation is a combination of depression and anxiety." Depression and anxiety are not diagnostically classified as separate disease that have different criteria as designated by the DSM according to this definition. Applicants respectively note that the DSM describes the co-morbidity of depression with respect to the anxiety.

Applicant, therefore, respectfully asserts that two independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Under M.P.E.P. §802.01 "independent" means "there is no disclosed relationship between the ... subjects disclosed, that is, they are unconnected in design, operation, or effect..." Applicants respectively request that the restriction requirement be withdrawn in view of the fact that the claims of the Groups I-II are not independent.

Accordingly, in view of the preceding remarks, applicant respectively requests that the Examiner reconsider and withdraw the

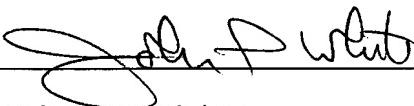
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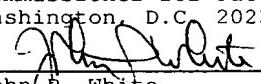
requirement for restriction.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided.

No fee, other than the enclosed fee of \$55.00 for a one-month extension of time, is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

  
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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.	
 11/26/02	Date
John P. White Reg. No. 28,678	